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## Inclusion of South African adolescents in HIV vaccine trials

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### Abstract

South Africa has more people living with HIV than any other nation. The HIV epidemic in South Africa is being driven by new infections among adolescents. Inclusion of adolescents in HIV vaccine trials is essential for successful vaccine development, however, recruitment and retention of at-risk South African adolescents into these trials poses a number of legal, ethical and operational challenges. This article discusses the South African ethico-legal context in which future adolescent HIV vaccine trials would be conducted followed by a review of available data regarding strategies for recruitment into these trials and retention of trial participants.

### Keywords

Adolescent; HIV vaccine trial; South Africa; recruitment; retention

## INTRODUCTION

In order to develop and license vaccines against the Human Immunodeficiency Virus (HIV) for use in adolescents, clinical trials of these vaccine candidates must include adolescent participants. Adolescents are an intrinsically critical target population for HIV vaccines since sexual activity, and therefore risk of exposure to HIV, often begins during this developmental period. According to UNICEF, in 2009, over 40% of new adult infections with HIV occurred in young people between the ages of 15 and 24, amounting to 890,000 new infections in that age group during that year (UNICEF, 2010).

Sub-Saharan Africa and South Africa in particular, bear a disproportionate burden of HIV infection. Over 70% of all young people living with HIV/AIDS live in Sub-Saharan Africa (UNICEF, 2010). More HIV infected people live in South Africa than in any other nation on Earth and South Africa has the fastest growing HIV epidemic in the world (McClure et al., 2004). Local research suggests that 76% of South African adolescent females (mean age 15) are sexually active (Kelly, 2002). The average age of sexual debut among South African adolescents has been reported as 14.6 years (Jaspan et al., 2006). Evidence indicates that the HIV epidemic in South Africa is being driven largely by new infections among adolescents – in particular, females (Dorrington, 2004). The national prevalence of HIV in under 20 year old females during antenatal testing has been reported as 16% (Middelkoop et al., 2008). Another South African study found the prevalence of HIV in the 14- to 16-year old age group to be 12% (Jaspan et al., 2006). Unfortunately the prevalence of HIV among 15–24 year old South African females continues to rise (Gouws et al., 2008).

Effective vaccination prior to sexual debut will curb the incidence of HIV among adolescents. In order to develop such a vaccine, clinical trials must include large numbers of at-risk adolescent participants. Although there are many challenges to the inclusion of South African adolescents in HIV vaccine trials, inclusion of this group into future trials is of

paramount importance. This article discusses the South African legal milieu in which adolescent HIV vaccine trials would occur, and reviews the literature surrounding recruitment and retention of South African adolescents into such trials.

## THE SOUTH AFRICAN CONTEXT

In South Africa, as elsewhere, children are broadly considered a vulnerable group and merit special protection under the law. While the intent of such legislation is to protect children from exploitation and ensure legal protection from abuse, it also has significant complicating ramifications for adolescent participation in HIV vaccine trials. While a detailed discussion of the South African constitution and legal system is well beyond the scope of this article, a review of certain relevant laws is necessary to appreciate the complexity of conducting research with adolescent subjects in South Africa.

According to South African law a minor may independently consent to medical treatment at age 14, use contraceptives at age 14, consent to HIV testing at age 14, and consent to termination of pregnancy at any age (Strode, 2005). However, according to the South African National Health Act (NHA) minors (i.e. under age 18) require parental or legal guardian consent to participate in research (Jaspan et al., 2008; Slack et al., 2007). Consent for research is further complicated by the South African government's distinction between therapeutic and non-therapeutic research. According to the NHA's Medical Research Council's *Guidelines on Ethics for Medical Research: General Principles*, "Non-therapeutic research on minors is not permissible except ... for observation research" (Slack and Kruger, 2005). Although the NHA does not clearly define therapeutic versus non-therapeutic research, HIV vaccine trials, which are likely to be conducted with healthy volunteers, might certainly be considered non-therapeutic. At the same time, they would presumably be invasive in nature and not purely observational, thus potentially at odds with the Medical Research Council's guidelines. This murky legal scenario could pose a fundamental threat to conducting any HIV vaccine trial involving adolescents in South Africa.

The issue of privacy is inextricably interwoven with issues of informed consent/assent and is particularly problematic as pertains to adolescent involvement in HIV vaccine trials. Sensitive topics such as sexual activity, use of contraception, elective termination of pregnancy, HIV infection, other sexually transmitted infections (STIs), and post-exposure prophylaxis (PEP) are likely to complicate the consent/assent process and render complete participant privacy untenable. The age of independent consent in South Africa is 18 years as dictated in the South African National Health Act (Jaspan et al., 2008; Slack et al., 2007).

For those adolescents younger than 18 years of age, parental or legal guardian consent is required and informed assent is required from the young study participant (definitions of the adolescent age range vary but for the purposes of this article will be considered to be 12–18). The South African age of lawful consent to sex, however, is 16, and evidence suggests that at least half of South African adolescents are sexually active by that age (Eaton et al., 2003). This discrepancy between age of legal consent to sex and age of legal consent to medical decision making and study participation set the stage further for complications related to privacy in the inclusion of South African adolescents in HIV vaccine trials

For an HIV vaccine trial to be efficient and informative, Adler 31 the trial's participants must have sufficient risk of acquiring HIV infection. The recruitment process and eligibility criteria (which may include sexual activity or exclude prospective participants with pre-existing STIs) will reflect this requirement for an at-risk sample. Since parents/legal guardians must be intimately involved in the consent/assent process for enrollment in such a trial, the privacy of the involved adolescent will not be fully protected. This may cause a

chilling effect on adolescent participation since many young people may not want their parents to know about their sexual activity and related issues. Moreover, as a trial progresses, continued monitoring of HIV status, as well as other STIs and measures of sexual activity, will be conducted. It would be difficult to protect an adolescent study participant's privacy when the consent for these measures must come from participants' parents or legal guardians.

In 2007, the South African Sexual Offences Act took effect. This Act reaffirmed the age of consent to sex at 16, and defined sex with a child age 12–16 as statutory rape. The Act also established a number of mandatory reporting requirements for adults that are aware of violations of the law including rape, statutory rape, child sex work, and child pornography (Strode, 2009). The Sexual Offences Act does not discriminate, however, between under-age sex that is non-consensual (i.e. rape), under-age sex that is consensual but likely to be exploitative (e.g. a 13 year old girl and a 30 year old man) and under-age sex that is consensual (e.g. two 15 year olds).

For example, if a schoolteacher were aware that a 15-year-old student was engaging in consensual sexual activity with her 15-year-old boyfriend, according to the letter of the law, he would be legally required to report this to the police. This has tremendous ramifications for adolescent participation in HIV vaccine trials. Sexual history taking as well as testing for STIs among study participants will provide proof of sexual activity in many adolescents. Will this information then compel the investigators to contact the police? This clearly presents challenges to recruitment.

These implications of the Sexual Offences Act for biomedical research with adolescents were likely unanticipated by legislators and are in apparent conflict with other South African laws. For example, the Children's Act established the rights of children under age 16 to access contraceptives and HIV testing without parental consent (Strode, 2009). This implies that the providers of these services would have to report all of their young clients to legal authorities since they are presumably engaging in "illegal" sex. This is clearly problematic.

Despite this complicated legal context, a fair amount of research has been conducted in South Africa related to the recruitment and retention of adolescents into future HIV vaccine trials. These studies provide insight into the behavioral barriers and enablers that may accompany the legal barriers and enablers presented above.

## **RECRUITMENT AND RETENTION: REVIEW OF THE EVIDENCE**

Much of the research conducted regarding recruitment and retention of adolescents into future HIV vaccine trials centers around willingness to participate (WTP). WTP research often strives to assess perceived barriers and facilitators of participation in addition to baseline self-reported WTP. The results of these WTP studies will inform future recruitment and retention efforts. Still, it is important to keep in mind that WTP is a very imperfect predictor of future successful recruitment and retention of adolescents into HIV vaccine trials.

In 2006, Jaspan and colleagues reported the results of a cross-sectional study that included HIV antibody testing and self-administered questionnaires regarding sexual risk behaviors and attitudes toward HIV vaccine trials (Jaspan et al., 2006). Among the 356 11–19 year old South Africans studied, 79% reported willingness to participate in an HIV vaccine trial. Increasing age and duration of residence in the study community were associated with willingness to participate. The study questionnaires used included questions aimed at determining the perceived barriers to participation in an HIV vaccine trial. Investigators reported that the most commonly reported barriers were fear of side effects (27%), fear of

getting HIV from the vaccine (23%), fear of needles (20%), too busy (11%), and fear of what others may think (8%).

In 2007, Middelkoop and colleagues reported the results of a cohort study in which baseline questionnaire on sexual risk behavior and willingness to participate in HIV vaccine trials were administered (Middelkoop et al., 2008). Follow up questionnaires were then administered after a series of three monthly HIV counseling and testing visits. This study included 200 16–40 year old South Africans thus enabling a comparison between adolescents and adults. At baseline they found that adults reported greater willingness to participate than adolescents (40 vs. 13%). After the educational intervention both rates increased (63 and 40% respectively). This study suggests that an educational intervention may increase WTP and subsequent recruitment in HIV vaccine trials but is limited by its lack of control group. Interestingly, this study also evaluated predictors of retention throughout the multi-visit study that may have some applicability to retention in future HIV vaccine trials. The authors reported that retention was associated with female gender and greater baseline knowledge of HIV for both adults and adolescents.

De Bruyn and colleagues reported the results of another South African questionnaire-based study in 2008 aimed at assessing adolescent WTP and factors that promote WTP (de Bruyn et al., 2008). They found that among the 240 respondents, 52.5% reported being “definitely willing to participate” and another 35% were “probably willing”. WTP did not differ significantly by gender or age. Importantly, the authors identified factors that were rated as “very important” by respondents regarding their WTP, including “receiving current information about HIV” (88.9%), “honoring people who have HIV or have died of AIDS” (70.9%), “getting free counseling and testing” (70.5%), “protection against HIV infection” (70.2%), and “improving motivation to avoid risky behavior” (59%). The fact that the majority of respondents are motivated by the prospect of protection against HIV suggests imperfect understanding of the unproven nature of vaccine candidates and the role of placebo groups in clinical trials. Still, this data is very valuable in constructing recruitment and retention strategies for future HIV vaccine trials.

In a significantly more technical and abstract approach to WTP, Giocos and colleagues assembled a convenience sample of 224 South African adolescents and administered questionnaires with the goal of using hierarchical logistic regression analysis to determine if the Theory of Planned Behavior (TPB) predicted WTP (Giocos et al., 2008). They found that “subjective norms” and “attitude towards participation”, as measured in a battery of TPB based questionnaires, significantly predicted WTP. “Subjective norms” are the research subjects’ perception of what others think, what is expected by others, and what others approve/disapprove of. Interestingly, the investigators’ model did not find that knowledge of HIV, perceived self-risk of HIV, or attitudes towards HIV/AIDS significantly predicted WTP. These findings underscore the importance of social stigma and perceived community views in an adolescent’s WTP.

It is fascinating to notice that while de Bruyn (de Bruyn et al., 2008) found that “receiving current information about HIV” was a strong predictor of WTP, and Giocos (Giocos et al., 2008) found that knowledge of HIV did not predict WTP, there is some evidence that knowledge of HIV is inversely related to WTP. Murphy and colleagues conducted a cohort study in which one group of adolescents received the standard information on HIV vaccine trials and another received a simplified version aimed at improving adolescent comprehension (Murphy et al., 2007). They found that while those who received the simplified version had significantly higher comprehension scores on follow-up evaluation, they also reported less WTP.

Most recently, a South African study was conducted to assess WTP after the discontinued Phambili Trial (Otwombe et al., 2011). In 2007, a large-scale phase IIB trial of an HIV vaccine candidate, known as the STEP trial, was discontinued due to evidence that the vaccine did not confer protection against HIV infection as well as a non-statistically significant suggestion that the vaccine may actually increase the risk of HIV acquisition among a particular sub group (Gray et al., 2010). In South Africa, a sister trial of the STEP trial, known as the Phambili Trial, was also stopped. The Phambili trial was the first large-scale phase IIB HIV vaccine trial to be conducted in South Africa. Approximately 800 adults were enrolled in the trial at the time it was stopped (Gray et al., 2010). No adolescents were enrolled in the Phambili trial, however, the unfavorable outcome of this trial could certainly have an impact on the WTP of South African adolescents in future HIV vaccine trials. In their interview-based study of over 500 South African adolescents, Otwombe and colleagues found that WTP was 75% for participation in a vaccine trial after learning about the fate of the Phambili trial. Unfortunately, those with the highest number of sexual partners, and therefore most likely at higher risk, had lower rates of WTP.

The widely ranging rates of WTP reported among these studies may relate to several factors. The way in which a vaccine trial is presented can vary considerably with differing emphases on risks, benefits, and the burden of trial participation. WTP may have been influenced by these differences in presentation among the studies. In addition, South Africa is an extremely diverse country and different community norms may have influenced the WTP findings among the different studies. Finally, results may vary due to the differing data collection techniques as self-administered questionnaires, researcher-administered questionnaires, and structured interviews could yield varying results. The literature on WTP touches upon but does not delve deeply into the issues of privacy that are inextricably wound up with consent. Only if this WTP is accompanied by consent and assent processes that are consistent with South African law and are acceptable to both prospective adolescent trial participants and their parent/legal guardian would trial participation be possible.

Although not a study of WTP in HIV vaccine trials, Sayles and colleagues utilized six focus groups comprised of South African adolescents to evaluate issues surrounding HIV vaccine acceptability (Sayles et al., 2010). Their findings that fear of vaccine side effects, fear of HIV testing, and mistrust of the scientific community all present barriers to HIV vaccine uptake have significant implications for WTP in vaccine trials as all of these factors are relevant in both scenarios. In another 2010 study utilizing focus groups from South Africa, high levels of parental support for adolescent participation in HIV vaccine trials was identified (Jaspan et al., 2010), a finding that would facilitate compliance with South African legal requirements.

Another relevant, although non-South African, study of adolescent participation in HIV research, was published by Stanford and colleagues in 2003 (Stanford et al., 2003). This study used self-administered questionnaires given to participants in a longitudinal observational study of HIV-infected adolescents (the REACH study) to assess which factors were most important to their recruitment and retention in the REACH study. Investigators found that the most important factors were the same for both recruitment and retention, namely: “quality medical care”, “caring staff”, “health education”, “privacy/confidentiality”, and “altruism”. The results of this study of HIV-infected U.S. adolescents in an observational study should be applied with caution to South African adolescents who are prospective HIV vaccine trial participants, but they are consistent with much of the South African data described above.

Finally, some lessons can be learned from the recent international clinical trials of the Human Papillomavirus (HPV) vaccines. HPV and HIV vaccine trials are similar in that both

address sexually transmitted infections, both would ideally target children prior to sexual debut, and both involve significant issues of privacy. In an opinion piece written in the wake of HPV vaccine approval, Garner points out certain “lessons learned” that may be applicable to the involvement of adolescents in future HIV vaccine trials (Garner, 2010). Garner attributes some of the success of the HPV vaccine trials to the provision of educational materials to adolescents and their parents. More important, however, was the explicit emphasis on confidentiality regarding sexual history accompanied by clear explanation of legal disclosure rules. In light of the complicated legal milieu in South Africa regarding mandatory reporting this observation is particularly interesting. The retention measure that Garner reports as effective include reminder cards, gift cards for health related items, and compensation for travel costs. Retention rates in the young adolescent trials of the quadrivalent HPV vaccine exceeded 90% (Garner, 2010).

## **DISCUSSION AND SUMMARY OF RECOMMENDED STRATEGIES**

Despite the challenges to inclusion of South African adolescents in HIV vaccine trials, several promising strategies for successful recruitment and retention are evident.

### **Education**

Educating and informing potential trial participants and their parents/guardians is required from the ethical standpoint, and is also supported by the evidence to be a positive factor for recruitment (Middelkoop et al., 2008). A recommended strategy to provide some of this education is through vaccine discussion groups in which investigators arrange for open forums at community focal points such as schools, churches or community centers during which information regarding HIV risk behaviors and HIV vaccine trials is provided. One study suggested that fear of getting HIV from the vaccine is a major barrier to participation (Jaspan et al., 2006). This type of unfounded fear should be addressed directly in an educational manner.

### **Community outreach and social messaging**

Evidence suggests that perceived social standards are important in determining an adolescent’s WTP in an HIV vaccine trial (Giocos et al., 2008). Positive and informative messaging should be distributed at community focal points aimed at reducing stigma that may be associated with participation in an HIV vaccine trial. The data provided by de Bruyn and colleagues (de Bruyn et al., 2008) indicates that effective social messaging in this population could include “honoring” others with HIV/AIDS, and use of trial participation as a portal to access HIV counseling and testing. It is important also, however, that prospective participants are not led to believe that access to health care will be denied to them if they choose not to participate. Capitalizing on the altruism that seems to be a major motivator in past vaccine trial participants as well as adolescent WTP can be done through social messaging that emphasizes the altruistic nature of study participation. Likewise, engaging community leaders such as youth group leaders, teachers, and coaches will assist in promoting recruitment by reducing stigma and bolstering positive motivations for participation.

### **Privacy and consent**

As discussed above, a tension exists between the requirements for participant privacy/confidentiality and parental consent. The consent process must include explicit delineation of the privacy privileges of the adolescent as well as situations in which privacy will be compromised due to the requirements of the consent process or mandatory reporting. There is significant evidence that privacy is a central issue for adolescents when considering their WTP (Giocos et al., 2008). It is likely that without sufficient privacy protection, recruitment

and retention of adolescents will be significantly impaired. One possible approach would be for enrollment to include a waiver of privacy rights by the adolescent, a waiver of access to certain sensitive information by the consenting parent/guardian, or some combination of the two. A pilot study that assesses the feasibility and impact of such waivers is recommended.

### **Compliance with law**

South African law complicates the inclusion of adolescents in HIV vaccine trials. Research staff must be well versed in legal aspects of sexual behavior and mandatory reporting requirements. Adolescents are allowed by South African law to independently consent to research participation at age 18 (Strode et al., 2011). Consensual sex is legal at age 16. Thus, to avoid putting investigators in a position where they are required to report statutory rape to legal authorities for many of their research participants, consideration of limiting these trials to adolescents age 16–17 should be considered. Unfortunately, many South African adolescents begin sexual activity prior to this age and would be ideal candidates for participation in an HIV vaccine trial but would be excluded under this approach.

### **Compensation**

Although a detailed discussion of the ethics of incentives in research is beyond the scope of this paper, it is recommended that no monetary incentives be provided. Compensation for travel expenses and time, however, are appropriate. Research suggests that travel is a likely barrier to recruitment and retention and compensation for travel expenses or taxi/bus vouchers may mitigate this barrier.

### **Health service access**

It is important to make clear to prospective study participants that access to health services will not be denied to those who choose not to enroll in a research study. Still, evidence suggests that a major motivator for participating in such research is access to care (de Bruyn et al., 2008). Recruitment and retention will likely be enhanced by ensuring that enrollees have ready access to adolescent health services such as HIV testing and counseling, STI testing and treatment, and pregnancy testing.

### **Additional strategies**

Some evidence suggests that recruitment and retention are facilitated by the same factors (Stanford et al., 2003). Still, there are certain techniques specific to retention that is likely to be valuable. Experiences from HPV trials with adolescents shows that travel compensation and reminder cards are helpful for retention. Pairing of trial participants may also improve retention, as pairs will reinforce each other's continued participation. Perhaps most importantly is a kind and caring research staff that endeavors to build relationship with study participants.

### **Conclusion**

South African adolescents constitute a promising at-risk population in which to conduct HIV vaccine trials. However, inclusion of South African adolescents in HIV vaccine trials presents many ethical, legal, and operational challenges. South African law presents a number of barriers to such research although a developing evidence base exists to guide recruitment and retention practices among this population. Key components of a successful strategy include education, protection of privacy with explicit acknowledgement of when it may be breached, and compliance with the law.

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